

REMARKS

Claims 1 to 72 are pending.

Present amendment cancels Claims 38 to 44, 48 to 56 and 62 to 72 without prejudice, amends Claims 1 to 4, 15, 17 to 23 and 25 to 32, and adds new Claims 73 to 76.

Applicants point out that all claims in the present amendment now provide that the pharmaceutical composition contains a disintegrant and must disintegrate within a specific period of time. Claim amendments and new Claims 73 to 76 find support in the specification at page 33, lines 16 to 22 and Example 15, at page 117, line 4 to page 118, line 4.

Applicants reserve the right to file continuation applications with claims directed to the subject matter of now-canceled Claims 38 to 44, 48 to 56 and 62 to 72.

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I. Rejections Under Judicially Created Doctrine of Obviousness-Type Double Patenting

The Office has rejected pending Claims 1 to 72 under the judicially created doctrine of obviousness-type double patenting over:

- (a) Claims 1 to 58 of commonly owned U.S. Patent No. 6,534,093;
- (b) Claims 1 to 65 of commonly owned U.S. Patent No. 6,410,054;
- (c) Claims 1 to 10 of commonly owned U.S. Patent No. 6,592,902;
- (d) Claims 1 to 62 of commonly owned U.S. Patent No. 6,558,707;

(e) Claims 1 to 21 of commonly owned U.S. Patent No. 6,495,165;

and provisionally rejected on the same grounds as being unpatentable over:

(f) Claims 1 to 60 of commonly owned copending Application No. 10/289,025; and

(g) Claims 11 to 13 of commonly owned copending Application No. 10/417,602.

As noted above, however, originally filed Claims 1-72 have now been cancelled or amended. Accordingly, the obviousness-type double patenting rejection is no longer applicable. Upon notification of allowable claims, Applicants will file a Terminal Disclaimer in compliance with 37 C.F.R. §§ 1.321(c) and 3.73(b), to facilitate prosecution of the pending application.

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II. Rejection Under 35 U.S.C. §101

The Office has rejected originally filed Claim 66 under 35 U.S.C. §101 as being directed to non-statutory matter. The present amendment cancels originally filed Claim 66, thus rendering the objection moot.

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III. Rejection Under 35 USC §103(a)

Independent, presently amended Claim 1 (to a pharmaceutical composition) and Claim 57 (to a method of using the pharmaceutical composition of Claim 1) both now require that the pharmaceutical composition comprises:

- (1) Eplerenone, in an amount from about 25 mg to about 100 mg, and
- (2) one or more pharmaceutically acceptable carrier materials, wherein at least one of the one or more carrier materials is a disintegrant,
- (3) wherein the composition is an immediate release composition that substantially disintegrates within about 14 minutes after being inserted in a water bath at a persistent temperature of 37°C ±2°C.

Originally filed Claims 1 to 72 were rejected under 35 USC §103(a), as being unpatentable over Grob, et al. ("Grob"), U.S. Patent No. 4,559,332, in view of G. Bernini ("Bernini"), U.S. Patent No. 4,332,721, and J. H. Fincher ("Fincher"), J. Pharmaceutical Sciences 57(11), 1825-35 (1968).

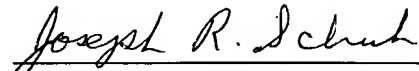
In view of the claim amendments submitted herein, a *prima facie* conclusion of obviousness over Grob, in view of Bernini and Fincher, has not been established. For example, none of these references, either alone or combined, teaches or even suggests all the claim limitations in the amended claims (MPEP § 2143).

Withdrawal of the rejection under 35 USC §103(a), as being unpatentable over Grob, in view of Bernini and Fincher is therefore respectfully requested.

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Favorable consideration and early allowance of pending claims is requested. Applicants respectfully request a three-month extension of time to and including April 1, 2005 for filing a response to the October 1, 2004 Office Action in this matter. The Commissioner is hereby authorized to charge the \$1020.00 fee for the requested three-month extension of time under 37 C.F.R. 1.17, together with any fees that may be required during the entire pendency of this application, to Deposit Account No. 19-1025.

Respectfully submitted,



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